

P338

GLUCOSAMINE/CHONDROITIN COMBINED WITH EXERCISE FOR THE TREATMENT OF KNEE OSTEOARTHRITIS: A PRELIMINARY STUDY

S.P. Messier¹, S.L. Mihalko¹, R.F. Loeser², J. Jolla¹, J. Pfruender¹

¹Wake Forest University, Winston-Salem, NC, ²Wake Forest University School of Medicine, Winston-Salem, NC

Purpose: This preliminary study sought to determine whether using 1500/1200 mg of glucosamine hydrochloride and chondroitin sulfate (GH/CS) is effective, both separately and combined with exercise, compared to a placebo-plus-exercise program in improving physical function, pain, strength, balance, and mobility in older adults with knee osteoarthritis (OA).

Methods: This double-blind, placebo-controlled, randomized clinical trial lasted 12 months. Participants included 89 older adults (age ≥ 50 yrs.) with knee OA randomized to either GH/CS or placebo groups. Phase I was a 6-month trial comparing the effects of assignment to either GH/CS or placebo. Phase II added 6 months of exercise for both groups. Outcome measures included WOMAC function and pain, 6-minute walk, balance, and knee strength.

Results: Of the 89 randomized participants, 72 (81%) completed the study. Pill compliance was 89% and 86% in Phase I, and in Phase II, 88% and 82% for the GH/CS and placebo groups, respectively. Exercise compliance during Phase II was 77% for the GH/CS group and 71% for the placebo group. WOMAC function and pain did not differ significantly between the groups at 6- or 12-month follow-up. The GH/CS group improved function 19% from baseline, while the placebo group improved 14%. Pain improved 10% and 22% in the GH/CS and placebo groups, respectively. Both groups made modest (5%) gains in 6-minute walk distance. Knee extension and flexion strength did not differ significantly between the groups. Balance improved 2% in the GH/CS group and 9% in the placebo group after 12 months. Rescue medication use decreased 37% in the GH/CS group compared to only 11% in the placebo group. An analysis of pill and exercise compliance revealed: (1) the high- and middle tertile-pill compliant GH/CS groups had 44% less pain ($p = 0.08$) than the lowest tertile; (2) the high exercise compliant GH/CS tertile had 34% greater knee strength ($p = 0.08$) compared to the low compliant tertile; (3) the high exercise plus 100% pill compliant GH/CS group performed better than all other GH/CS groups in function ($p = 0.07$), strength ($p = 0.04$), and balance ($p = 0.007$); and (4) for the high pill and the high exercise placebo tertiles, only 6-minute walk distance exhibited improvements ($p = 0.08$) relative to the lowest tertiles.

Conclusions: The use of glucosamine hydrochloride plus chondroitin sulfate, either alone or with structured exercise, results in modest improvements in function, pain, and mobility that are similar to results with a placebo. However, GH/CS therapy reduced the use of rescue medication three-fold compared to the placebo. High pill compliance and high exercise compliance proved beneficial for participants in the GH/CS cohort, and the combination of high exercise and 100% pill compliance showed the best overall improvements.

P339

FIRST RESULTS ON JOINT DISTRACTION IN THE TREATMENT OF SEVERE KNEE OSTEOARTHRITIS

A.C. Marijnissen¹, P.M. van Roermund², F. Intema¹, J.W. Bijlsma¹, F.P. Lafeber¹

¹UMC, Rheumatology & Clin. Immunology, Utrecht, The Netherlands, ²UMC, Orthopedics, Utrecht, The Netherlands

Purpose: Joint distraction demonstrates prolonged clinical efficacy in the treatment of severe ankle and hip osteoarthritis (OA). The present study describes the first results on joint distraction in severe knee OA.

Methods: Patients with severe posttraumatic OA of the tibio-femoral joint, who were considered for an endoprosthesis were treated with joint distraction. An external fixation frame bridging the knee joint was placed. Joint distraction was performed gradually until 5mm was reached (controlled on radiographs). Intra-articular fluid pressure changes, expected to be required for cartilage nutrition, were measured in the joint during distraction. The required absence of mechanical load on the cartilage, preventing further wear and tear, was controlled on standardized radiographs. Pain, functional disability, clinical condition, and flexion of the joint were evaluated using a box-scale, a questionnaire (slightly modified WOMAC) and by physical examination. A first rough estimation of costs was compared to that of joint replacement surgery.

Results: Six patients (48 ± 3 yr) with severe posttraumatic OA have been treated, for 3 ($n=3$) or 2 ($n=3$) months. Mean intra-articular fluid pressure was 1.1 ± 0.2 kPa during relaxation and 8.2 ± 2.4 kPa during loading (similar to ankle distraction). Mechanical load on the cartilage was absent during distraction, as was shown on radiographs. Pain and disability were very high before treatment for all 6 patients, $75 \pm 5\%$ and $64 \pm 7\%$ of the maximum score, respectively. Pain decreased significantly one year after treatment to $14 \pm 6\%$, while disability decreased to $7 \pm 3\%$ of the maximum score. Clinical condition was worse before treatment, $34 \pm 9\%$ of the maximum score, and increased to $88 \pm 7\%$. Flexion of the knee remained normal. No differences were found in clinical efficacy of a 2- or 3- month distraction period one year after treatment. The clinical efficacy persisted during the second year of follow-up. Joint distraction as described was calculated to be more than 1.500 € cheaper than the 1st joint replacement surgery.

Conclusions: During joint distraction of the OA knee, intra-articular fluid pressure was maintained while mechanical load on the cartilage was absent, a combination considered to be important for cartilage repair. Clinical efficacy was surprisingly quick and good (almost complete normalization) and lasted for up to 2 years now. Assuming clinical efficacy is remaining (for ankle OA 10 years profit has been demonstrated) knee distraction in case of severe OA is a very promising treatment and with that a prolonged prospective multi-center study is justified.

P341

EVALUATION OF ARTICULAR CARTILAGE FROM OSTEOARTHRITIC FEMORAL HEADS USING THE OARSI GRADING SYSTEM

M.C. Niesen¹, J.M. Hoffmann², H.F. Stampfli², M.W. Squire², L.D. Kaplan²

¹University of Wisconsin School of Medicine and Public Health, Madison, WI, ²Department of Orthopedics and Rehabilitation, University of Wisconsin, Madison, WI

Purpose: The grading of osteoarthritic cartilage has been based on limited grading systems and imaging techniques. The newly developed OARSI grading system (Osteoarthritis Research Soci-